

50-
CLAIMS

What is claimed is:

1. A unit dose composition for inducing angiogenesis in a human, comprising about .008 mg to about 7.2 mg of FGF-2 or an angiogenically active fragment or mutein thereof in a pharmaceutically acceptable carrier.
- 2 The unit dose composition of claim 1, comprising 0.3 mg to 3.5 mg of FGF-2, or an angiogenically active fragment or mutein thereof.
3. The unit dose composition of claim 1, wherein said FGF-2 has the amino acid sequence of SEQ ID NO: 2.
4. The unit dose composition of claim 3, comprising 0.3 mg to 3.5 mg of an FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof in a pharmaceutically acceptable carrier.
5. The unit dose composition of claim 3, comprising about .008 mg to about 7.2 mg of said angiogenically active mutein of said FGF-2 of SEQ ID NO: 2 in a pharmaceutically acceptable carrier.

054200" 4758E60

5 7. The unit dose composition of claim 3, comprising about
 .008 mg to about 7.2 mg of said angiogenically active fragment of said FGF-2 of
 SEQ ID NO: 2 in a pharmaceutically acceptable carrier.

9. The unit dose composition of claim 3, comprising about .008 mg to about 7.2 mg of FGF-2 of SEQ ID NO: 2 in a pharmaceutically acceptable carrier in a pharmaceutically acceptable carrier.

10. A method for treating a human patient for coronary artery disease comprising, administering a safe and therapeutically effective amount of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof to one or more coronary vessels or to a peripheral vein in a human patient in need of treatment for said coronary artery disease, said therapeutically effective amount being about 0.2 $\mu\text{g/kg}$ to 48 $\mu\text{g/kg}$ of patient weight.

2
11. The method of claim 10, wherein said recombinant FGF-2 has the amino acid sequence of SEQ ID NO: 2.

Sub D2/5
12. The method of claim 11, further comprising the step of administering to said human patient about 10 U/kg to 80 U/kg of heparin within about 0 to 30 minutes prior to administering said recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or mutein thereof.

6543210
Sub B3/10
13. The method of claim 12, wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof is administered to one or more coronary vessels.

Sub D4/15
14. The method of claim 13, wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof is about 24 µg/kg to 48 µg/kg.

Sub B4/20
15. The method of claim 12 wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or mutein thereof is administered to a peripheral vein.

55

Sub D⁶

16. The method of claim 15, wherein said therapeutically effective amount of a recombinant FGF-2 of SEQ ID NO: 2 or said angiogenically active fragment or mutein thereof is about 18 µg/kg to 36 µg/kg.

Sub D⁵

17. A method for treating a human patient for coronary artery disease comprising, administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof to one or more coronary vessels or to a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

65230-474930

Sub D⁸

18. The method of claim 17, wherein said FGF-2 has the amino acid sequence of SEQ ID NO: 2.

15

19. The method of claim 18, wherein said single unit dose produces a therapeutic benefit in said human patient that lasts at least four months.

sk
a²

20

20. The method of claim 19, wherein said single unit dose produces a therapeutic benefit in said human patient that lasts 6 months.

21. The method of claim 20, wherein said single unit dose produces a therapeutic benefit of such magnitude and duration in said human

SN
a
con
patient such that administration of a second unit dose is not required for about 6 months.

22. The method of claim 20, wherein said unit dose is administered to one or more coronary arteries.

23. The method of claim 20, wherein said unit dose is administered to a peripheral vein.

24. The method of claim 20, wherein said unit dose comprises 0.3 mg to 3.5 mg of a recombinant FGF-2 of SEQ ID NO: 2 or an angiogenically active fragment or mutein thereof.

15
25. The method of claim 19, further comprising the step of administering 10 U/kg to 80 U/kg of heparin to said patient IV or IC about 0 to 30 minutes prior to administering said unit dose.

20
26. A method for inducing angiogenesis in a heart of a human patient comprising, administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof to one or more coronary vessels or to a peripheral vein in a human patient in need of treatment for coronary artery disease, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

Sub D" 27. The method of claim 26, wherein said FGF-2 has the amino acid sequence of SEQ ID NO: 2.

5 ¹⁹/₂₈ The method of claim ¹⁸/₂₈ wherein said single unit dose produces an improvement in one or more clinical endpoints in said human patient that lasts at least four months.

10 ²⁰/₂₈ The method of claim ¹⁹/₂₈, wherein said single unit dose produces an improvement in one or more clinical endpoints in said human patient that lasts 6 months.

15 ¹⁸/₂₈ 30. A method for treating a human patient for a myocardial infarction comprising, administering a single unit dose of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof to one or more coronary vessels or to a peripheral vein in said human patient, said unit dose comprising from about .008 mg to 7.2 mg of a recombinant FGF-2 or an angiogenically active fragment or mutein thereof.

20 ¹⁸/₂₈ 31. The method of claim 30, further comprising the step of administering 10 U/kg to 80 U/kg of heparin to said patient IV or IC about 0 to 30 minutes prior to administering said unit dose.

56

Sub D^B

32. The method of claim 31, wherein FGF-2 has the amino acid sequence of the SEQ ID NO: 2.

HL B91

33. The method of claim 30, wherein said unit dose is administered to a peripheral vein.

25

21

34. The method of claim 30, wherein said unit dose is administered into one or more coronary vessels of said patient.

add a₃

add B11

09385144 082799

97